Regulatory Affairs Manager, GDD-Morocco

Job ID
REQ-10049269

4月 17, 2025

Morocco

摘要

Set strategy, and manage registration dossiers of new products, line extensions and new indications. In addition to maintain license of existing registered products by managing of all regulatory activities throughout product lifecycle.

About the Role

Major accountabilities:

- Leads implementation of the defined global and regional registration strategy into country submissions.
- Coordinates, plans and prepares for submission of initial registrations and post approval applications.
- Lead regulatory activities during HA reviews, responding to questions and HA interactions.
- Create/ Supervise in the creation, maintenance, review & approval of artworks in line with the

approved information by the HAs in the artwork management system
- Review, approval of Promotional and Non-Promotional Material for assigned products according to Novartis policy and guidelines and applicable local regulation, submission to HAs when applicable.
- Ensure compliance with local regulation and adherence to Global and local processes during daily regulatory activities:
- Ensures timely RA input and monitoring of regulatory compliance and maintenance reports, maintaining regulatory information in compliance databases and documenting Regulatory Information Management systems.
- Manage/ Support HA inspections, global GMP & PV audits, self-assessment, deviations, quality events and respond adequately to all requests about regulatory area.

Key performance indicators:

- The timely registration of new drug products, line extensions, new indications.
- Accurate & timely maintenance of products life cycle management.
- Good governance and Oversight of third parties KPIs
- Compliance of the promotional materials with the registered/approved PI.
- High regulatory compliance percentage for all relevant databases.
- Keep the relation with all related parties (inside & outside NVS) at the top level of respect, confidence & reliability.

Minimum Requirements:
Work Experience:

- Pharmacist with 5-7 years of experience in Regulatory Affairs.
- An experience in similar position with management is desired.
- Functional Breadth.
- Cross Cultural Experience.
- Operations Management and Execution.
- Project Management.

Skills:

- Registration strategies
- Detail Oriented.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- Regulatory Compliance.

Languages :

- English is a must

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部门
Development

Business Unit
Universal Hierarchy Node

地点
Morocco

站点
Casablanca

Company / Legal Entity
MA03 (FCRS = MA003) Novartis Pharma Maroc SA

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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